

*\*Product ingredient source information may be entitled to confidential treatment\**

**DATE OUT:** 21/June/ 2007

**SUBJECT:** **PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**  
**DP BARCODE No.:** D337849 **EPA Reg. No.:** 2749-523a  
**PRODUCT NAME:** Aceto Asulam 400 Herbicide  
**COMPANY:** Aceto Agriculture Chemicals Corp.  
**FOOD USE [X] INTEGRATED FORMULATION [ ]**  
**PCC:** 106902 **Decision No.** 375232 **ACTION CODE:** R34

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*YME 6/21/07*  
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**TO:** Eugene Wilson / Joanne Miller, RM 23  
Herbicide Branch / RD (7505P)

**INTRODUCTION:**

The Registrant has submitted a second basic CSF dated February 22, 2007 for the above mentioned end-use product. The product chemistry data submitted previously for the original basic formulation have been reviewed by TRB and was found acceptable on 03/02/2006. The product was registered on 03/17/2006. The product is manufactured by [REDACTED]. The technical active ingredient is not registered with the Agency.

The proposed new basic formulation (CSF dated 02/22/2007) allows a second source of the technical sodium salt of asulam. The second source is from [REDACTED]. Product chemistry data corresponding to Subgroup A and Subgroup B were submitted in support of the second source (MRID Nos. 470642-01 and 470642-02) and product chemistry data were also submitted under MRID Nos. 466000-01, 466000-02, and 466000-03 for first formulation, CSF dated 3/2/2006. TRB is requested to evaluate product chemistry data submitted in support of an amendment of the registration of this pesticide product to replace the basic formulation with one that has an added source of the active ingredient and was dated February 22, 2007.

This review of the subject formulation supersedes the previous product chemistry review dated May 29, 2007.

**SUMMARY OF FINDINGS**

1. The subject end use formulation contains one active ingredient: Asulam sodium salt (88.6%).
2. The source material of the active ingredients in the end use product is not registered with the Agency.
3. The nominal concentration of the active ingredient is 36.2%. The certified limits of the nominal concentration are in compliance with 40 CFR§ 158.175 (b) (2).
4. The CSF of the new basic formulation (dated 02/22/2007) is filled out correctly & completely. The nominal concentration of the active ingredient matches with the label claim. This is in compliance with PR Notice 91-2.

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5. The product chemistry data submitted for Subgroup A for the original basic formulation was reviewed by TRB and was found acceptable (03/02/2006). Chemically similar source material and similar process is used for manufacturing the new basic formulation. Therefore, product chemistry data for Subgroup A will be acceptable from the old formulation for registration of the new basic formulation [MRID Nos. 466000-01, -02, and 03].

6. The product chemistry data found acceptable on March 2, 2006 for Subgroup B of the original basic formulation will satisfy the product chemistry data requirements for the new basic formulation, with the exception of storage stability (830.6317) and corrosion characteristics data (830.6320). There was a data gap for storage stability and corrosion characteristics data in the original basic formulation.

#### **CONCLUSIONS:**

1. TRB has reviewed the CSF of the new basic formulation (dated 2/22/2007) and has found it to be acceptable. This shall supersede the original basic formulation dated 2/28/06.

2. The product chemistry data submitted for the guidelines 830 Series Subgroup A and Subgroup B, with the exception of storage stability (830.6317) and corrosion characteristics (830.6320), are acceptable.

3. The registrant shall generate one year storage stability (830.6317) and corrosion characteristics (830.6320) data on the proposed product. It is recommended that the observations be made at 0, 3, 6, 9, and 12 month intervals. The results must be submitted to the Agency in the electronic format and as well as a hard copy.

4. Discussion on impurities (4830.1550)

The original basic formulation (CSF dated 2/28/2006) and the new basic formulation (CSF dated 2/22/2007) are different in composition and concentration of the active material.

Compositional difference:

In addition to the three common impurities in the active ingredient that exist in the original basic and the new basic formulation; the proposed basic formulation contains [REDACTED] impurity.

Difference in concentration:

The total impurities in the original basic formulation are [REDACTED] as stated in that CSF whereas the new basic formulation contains [REDACTED] impurities in the asulam sodium salt.

*\*Manufacturing process information may be entitled to confidential treatment\**

**Discussion and recommendation:**

A. The proposed basic formulation is not identical to the original basic formulation because of differences in the impurity profile [FIFRA § 3 (c) (3) (B) (I)].

B. The proposed basic is not substantially similar to the original basic because it contains an impurity of toxicological concern. This impurity may significantly increase the risk of unreasonable adverse effects on the environment and health [FIFRA § 3 (c) (3) (B) (I)]. The registrant is required to address the toxicological significance of impurities when submitting amendment to the Agency, but no information in that regard was presented with the submitted documents.

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PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A Subgroup B)

Subgroup A	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
830.1550. Chemical Identity (not registered & same as in Product CSF)	A	466000-01, 470064-01
830.1600. Beginning Materials	A	470642-01
830.1620. Production Process	A	466000-01, 470642-01
830.1670. Discussion of Impurities	A	466000-01
830.1700. Preliminary Analysis	A	466000-02, 470642-02
830.1750. Certified Limits (Basic CSF dated 2/22/2007)	A	470642-01
830.1800. Enforcement Analytical Method	A	466000-02, 470642-02

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Herbicide (adapted from the review of original basic formulation dated 3/2/2006)

Subgroup B	<u>Data Required Fulfilled</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
830.6302. Color	A	Off-white	466000-03
830.6303. Physical State	A	Solid-powder	466000-03
830.6304. Odor	A	Odorless	466000-03
830.6313. Stability to normal and elevated temp, metals and metal ions	A	No breakdown of AI	466000-03
830.6314. Oxidation/Reduction action	W		
830.6315. Flammability (basic CSF 2/22/06)	W		
830.6316. Explodability	W		
830.6317. Storage stability	G		
830.6319. Miscibility	W		
830.6320. Corrosion Characteristics	G		
830.6321. Dielectric Breakdown Voltage	W		
830.7000. pH	A	7.03	466000-03
830.7100. Viscosity	A	4.4 & 2.7mPa sec @ 20.0° & 37.8° C	466000-03
830.7000. Density/Bulk Density	A	1.18 g/ml	466000-03 & CSF (dated 2/22/07)

**Explanations:** A = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled; NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W = Waived.

